AMENDMENTS TO THE DRAWINGS

Please replace Replacement Figures 8 and 9 (Sheets 8 and 9), filed March 22, 2005, with the Replacement Figures submitted herewith.

Attachment: Replacement Sheets 8 and 9

REMARKS

Status of the Claims and Amendment

Claims 1-8 and 13-21 are all the claims pending in this application. Claims 11 and 12 will be canceled. New claim 21 will be added. Support for the newly added claim 21 can be found at pages 23 and 24 of the present specification.

Claim 3 has been amended to delete "raloxifene L-lactate ¼-hydrate being."

Claim 4 has been amended to remove the recitation of "acid addition salt or solvate thereof according to claim 1, wherein the raloxifene acid addition salt or solvate thereof is raloxifene " and replace the term "hemihydrate" with the term "anhydrate." Support for the amendment to claim 4, namely replacing "anhydrate" with "hemihydrate" can be found in an executed Declaration under 37 C.F.R. § 1.132, submitted herewith.

In addition, a Substitute Specification and the Drawings are submitted herewith. The amendments to the specification and the drawings are supported by an executed Declaration under 37 C.F.R. § 1.132, submitted herewith. Namely, in view of developments within the area of analysis techniques the terms "hemihydrate" and "¼-hydrate" have been deleted.

Entry of the above amendments is respectfully requested.

No new matter is added by way of this amendment.

I. Claim of Priority

Applicants respectfully request that the Examiner acknowledges Applicants' claim to foreign priority, namely, PA200201450, and confirm that a certified copy of the priority document has been received by the Office.

II. Response to claim 4 rejections under 35 U.S.C. § 112, second paragraph

On page 2 of the Office Action, claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly encompassing several solvates.

Without conceding the merits of the rejection, Applicants respectfully submit that claim 4 has been amended, therefore obviating the rejection.

Additionally, the Examiner is unclear as to what are the d-space or 2Θ drawn to; a mixture of homochrial crystal or a heterochiral crystal of paired R- and S- in the unit cell.

Applicants respectfully submit that that the claimed DL form relates to a racemic compound, wherein the two constituent enantiomers coexist as pairs in the same unit cell of the crystal lattice, and does not relate to an equimolar physical mixture of the D and L enantiomers. As the XRD patterns of a racemic compound and a physical mixture would be different from each other, it would seem clear that defining the DL form by its XRD pattern, as recited in claim 4, immediately distinguishes between these two possibilities. In this regard, as stated by the Examiner, "[t]he claimed DL raloxifene lactate can only be one or the other." *See* Office Action page 3, lines 5-6. This is supported by the presence of only one set of XRD data, which would be recognized by one of ordinary skill in the art as related to only one form. Accordingly, one of ordinary skill in the art would not assume that claim 4 covers a physical mixture of racemates. In this regard, Example 4 of the application as filed relates to a method of making the DL-lactate. This method will only result in one form, the claimed DL racemic compound. Accordingly, one of ordinary skill in the art would understand the scope of the claim.

In view of the above, withdrawal of the rejection is respectfully requested.

III. Response to claim 4 and 11-12 rejections under 35 U.S.C. § 112, first paragraph

1. On page 2 of the Office Action, claim 4 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement, for partially the same reasons as set forth above.

Specifically, the Examiner is unclear as to what are the d-space or 2Θ drawn to; a mixture of homochrial crystal or a heterochiral crystal of paired R- and S- in the unit cell.

Applicants respectfully traverse the rejection.

In response, Applicants note that as previously argued above, it is understood by one of ordinary skill in the pertinent art that the claimed DL form relates to a racemic compound, wherein the two constituent enantiomers coexist as pairs in the same unit cell of the crystal lattice, and does not relate to an equimolar physical mixture of the D and L enantiomers. Again, Example 4 relates to a method of making DL-lactate and thus, it is respectfully submitted that the present invention is enabled.

Accordingly, withdrawal of the rejection is respectfully requested.

2. On page 3 of the Office Action, claims 11-12 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

In this regard, the Examiner asserts that it is not demonstrated that the claimed pharmaceutical compositions will actually retain the crystalline form of the original compound represented by the X-ray crystalline positions, as recited in independent claim 4.

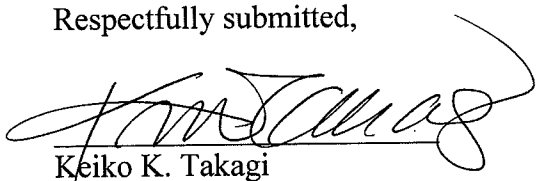
Without acquiescing the merits of the rejection, claims 11 and 12 have been canceled. Accordingly, the rejection is rendered moot with regard to claims 11 and 12.

IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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